UNITED STATES PATENT AND TRADEMARK OFFICE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _26 August 2005_.
2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-53_ is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) _1-47 and 50-53_ is/are rejected.
7)☒ Claim(s) _48 and 49_ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☒ All   b)☐ Some * c)☐ None of:
      1.☒ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _07/11/2007_.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 13 is objected to because of the following informalities: The "n" is omitted from

the supposed term "n7". Appropriate correction is required.

35 USC 101 – Claim Rejection

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 52 is rejected under 35 U.S.C. 101 because the claimed invention is directed to

non-statutory subject matter. In claim 52, regarding "computer program product

comprising computer program instructions", a "program" is being recited; however,

computer program would reasonably be interpreted by one of ordinary skill in the art as

software, per se.   This subject matter is not limited to that which falls within a statutory

category of invention because it is limited to a process, machine, manufacture, or a

composition of matter. Software is a function descriptive material and a function

descriptive material is non-statutory subject matter. Examiner suggests that the

applicant replace "a program" with – computer readable medium storing computer

executable instructions. Also, note that the computer readable medium should be

described somewhere in the specifications so that it will fall into a statutory category and

not be interpreted as a signal for example.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-13 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6, the limitation "and/or" is used, but appropriate support is not found in the specification. This interpretation should be accompanied by three separate embodiments in the specification. Two of these embodiments should require either the ventricle or the body exclusively, and one embodiment should require the use of both. Analogous arguments are made for claim 11.

As per claims 8-9, 12, 13, 16, 17, 20-22, 25, 26, 30-32, the term "around" is indefinite since one cannot be sure of the intended variance required by the claim language. For the purpose of this office action, this variance is interpreted to mean that the value is on the same order of magnitude such that the same metric units are used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-34, 36-47, and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Automatic Segmentation of the Ventricular System from MR Images of the Human Brain", NeuroImage 2001, May 2001, Vol. 14, pages 95-104 (Schnack) and USPGPubN 20030068074 (Hahn).

As per claim 1, Schnack teaches a method for extracting cerebral ventricular system information from images of one or more cerebral ventricular regions, the cerebral ventricular system comprising a third ventricle (V3), a fourth ventricle (V4), a left lateral ventricle (VLL) having a body (VLL-B) and an inferior (temporal) horn (VLL-I'), a fight lateral ventricle (VLR) having a body (VLR-B) and an inferior (temporal) horn (VLR-I), an anterior commissure (AC), a posterior commissure (PC), and a midsagittal plane (MSP), the method comprising the steps of **(Limitations present only within the preamble are not given patentable weight)**:

1) defining multiple regions of interest (ROI) in-the images **(Schnack: page 96, col 2, para 2: "The total brain segmentation is a binary image, consisting of voxels with value 1 at places with brain tissue and voxels with value 0 at other places: cerebrospinal fluid (CSF) and all other voxels surrounding the brain. The remaining and most complex part of the problem is the classification of the correct zero-valued voxels in the total brain image as ventricular CSF.");**

2) defining seed points within each ROI **(Schnack: page 97, col 1, para 1: "starting**

points of two region-growing operations"; page 98, col 2, para 1: "seed points";

page 98, col 1, para 2: "seed points");

3) growing images of ventricular regions while correcting for leakages into

extraventricular space **(Schnack: Fig. 1: "close leak"; page 97, col 1, para 1 – col 2,**

para 1: "We use a unidirectional downward (increasing z) 3-D region-growing

operator, which prevents possible leaks to cisterns and sulci from migrating

upward. Slice by slice the grown areas are examined upon leaking."). Schnack

does not teach connecting the ventricular regions grown.

Hahn teaches connecting the ventricular regions grown **(Hahn: Fig. 1: 126-130; Figs. 3**

and 4).

Thus, it would have been obvious for one of ordinary skill in the art at the time the

invention was made to implement the teachings of Hahn into Schnack since Schnack

suggests a system for segmenting ventricular regions in brain images in general and

Hahn suggests the beneficial use of a system for segmenting ventricular regions in

brain images wherein the grown regions are connected (Hahn: 9page 4, paras 57 and

58) in the analogous art of image processing. It would have been obvious for one of

ordinary skill in the art at the time the invention was made to implement the connecting

of the grow regions since "The ventricular system is a connected structure and could,

therefore, in principle, be segmented with one region-growing operation", as stated by

Schnack (page 2, col 2, para 2). It is common an obvious to use multiple starting seed-points to segment a single and connected region of interest since "owing to the partial volume effect, parts of the system appear not connected on the image" (Schnack: page 2, col 2, para 2).

As per claim 3, Schnack in view of Hahn teaches a method according to claim 1 or 2 wherein the method is performed from one or more **(interpreted that only one is required)** medical imaging modalities **(Schnack: abstract: "MR images"; introduction: page 95: col 1: para 1: "MR imaging")**.

As per claim 4, Schnack in view of Hahn teaches a method according to any one of the preceding claims, wherein the step of defining multiple ROIs comprises defining each ROI in a predetermined plane **(Schnack: page 96, col 2, para 1: "For segmentation of the third ventricle, the coordinates of the anterior commissure (AC) and posterior commissure (PC) are needed"; Fig. 1: "the third ventricle W3), limited by the AC plane and the PC plane"; page 97: col 2, para 1: "If such a region crosses the midsagittal plane of the brain, this region is considered to be cistern")**.

As per claim 5, Schnack in view of Hahn teaches a method according to claim 4, wherein the step of defining multiple ROIs comprises selecting said predetermined plane to be on a coronal orientation to constitute a coronal slice **(Schnack: page 99, col 1, para 1: "The anterior and posterior boundaries are given by the coronal (zx)**

**planes through the anterior commissure (AC) and posterior commissure (PC),
respectively"; page 101, col 1, para 2: "Tl-weighted scans with 160-180 1.2-mm
contiguous coronal slices").**

As per claim 6, Schnack in view of Hahn teaches a method according to claim 5,
wherein the step of selecting said predetermined plane to be on a coronal orientation for
assessment of an image of the body of the left lateral ventricle and/or the body of the
right lateral ventricle comprises the steps **(Limitations present only within the
preamble are not given patentable weight)**:
(1) selecting the coronal plane (VAC) passing through the anterior
eommissure(AC) **(Schnack: page 99, col 1, para 1: "The anterior and posterior
boundaries are given by the coronal (zx) planes through the anterior commissure
(AC) and posterior commissure (PC), respectively");**
(2) selecting the initial rectangular ROI on the VAC laterally between the coordinates
[MSP, MSP+nl] for the body of the left lateral ventricle, and [MSP- nl, MSP] for the body
of the right lateral ventricle, and dorsally between [AC, AC+n2], where nl and n2 are
constants **(Schnack: page 99, col 1, para 1: "The anterior and posterior boundaries
are given by the coronal (zx) planes through the anterior commissure (AC) and
posterior commissure (PC), respectively. The superior boundary is given by a
plane through the plexus choroideus and ventriculi tertii in the midsagittal slice
perpendicular to this this slice");**

(3) altering the ROIs for subsequent processing based on desired histogram

distribution within the ROIs **(Schnack: page 101: col 2, para 1: "We used a series of**

mathematical morphology operators based upon intensity histogram analysis of

the image (Schnack et al., 2001). A coarse white matter segmentation was

obtained autornatically by thresholding the Tl-image with an intensity value

roughly between the gray and white matter peaks in the histogram.").

As per claim 7 and 8, arguments made in rejecting claim 1 are analogous to arguments

for rejecting claim 7 and 8.

As per claim 9, Schnack teaches a method according to any one of claims 6 to 8,

wherein n1 is around 25 mm **(Schack: page 96, col 1, para 2 – col 2, para 1)**.

As per claims 10, 12, 13, 16, 17, 20-22, 25, 26, 30-32, 41, arguments made in rejecting

claim 9 are analogous to arguments for rejecting claims 10, 12, 13, 16, 17, 20-22, 25,

26, 30-32, 41.

As per claims 11, 14, and 18, arguments made in rejecting claim 6 are analogous to

arguments for rejecting claims 11, 14, and 18.

As per claim 15 and 19, arguments made in rejecting claim 1 are analogous to arguments for rejecting claim 15 and 19.

As per claim 24, Schnack in view of Hahn teaches a method according to any preceding claim, wherein the step of defining seed points for within an ROI for V'LL-B and VLR-B comprises the steps **(Limitations present only within the preamble are not given patentable weight)**:

where n13 and n14 are constants to form ample line segments; 2) calculating a profile along each sample line segment; 3) determining the longest CSF segment from said profile; and 4) placing the seed point in the middle of the segment **(Schnack: page 96, col 2, final paragraph – page 97, col 1, para1; Fig. 1; page 98: col 1, para 1- col 2, para 1)**.

Schnack does not teach sampling the ROI horizontally, starting from AC+nl3 every n14 distance.

Hahn teaches sampling the ROI horizontally, starting from AC+nl3 every n14 distance **(Hahn: page 5, para 86)**.

As per claims 27-29, arguments made in rejecting claim 24 are analogous to arguments for rejecting claims 27-29.

As per claim 34, Schnack in view of Hahn teaches a method according to any preceding claim, wherein the step of growing the image of the third ventricle V3 comprises the steps **(Limitations present only within the preamble are not given patentable weight)**: 1) subdividing V3 into four subregions 1, 2, 3 and 4 by the planes passing VAC,

VPC, AC-PC, subregion 1 containing the most anterior part of V3 and being separated from subregions 2, 3 and 4 by the VAC and the AC-PC planes, subregion 2 containing the most dorsal part of V3 and being separated from the subregions 1, 3 and 4 by the AC-PC and the VPC planes, subregion 3 containing the most posterior part of V3 and being separated from subregions 1, 2 and 4 by the AC-PC and the VPC planes, and subregion 4 containing the most ventral part of V3 and being separated from the subregions 1, 2, and 3 by the AC-PC and theVAC planes; and 2) growing V3 in three dimensions, wherein subregion 1 is grown anteriorly on coronal slices, subregion 2 and subregion 3 are grown superiorly on axial slices; and subregion 4 is grown inferiorly on axial slices from the seed point **(Schnack: page 98, col 2, para 3 – page 99, col 1, para 1)**.

As per claim 33, arguments made in rejecting claim 34 are analogous to arguments for rejecting claim 33.

As per claim 40, Schnack in view of Hahn teaches a method according to claim 34,

wherein during the growth of the V3 region

the step of correcting for leakages posteriorly through the PC (stalk of the pineal

body) to the cistema ambiens, comprises**(Limitations present only within the**

preamble are not given patentable weight):

1) limiting the maximum width of foreground region of subregion 3 on an axial

slice to be on PC line; and 2) maintaining the distance between the centre of gravity of

the foreground region of subregion 3 and the MSP less than n18, where n18 is a

predetermined constant **(Schnack: page 97 – page 99)**.

As per claims 36-39 and 41-47, arguments made in rejecting claim 40 are analogous to

arguments for rejecting claims 36-39 and 41-47.

As per claim 51, Schnack in view of Hahn teaches an apparatus according to claim 50,

wherein the apparatus is a computing apparatus **(Schnack: page 99, col 1, para 2 -**

col 2, para 1: "IMPLEMENTATION").

As per claims 50 and 52, arguments made in rejecting claim 51 are analogous to

arguments for rejecting claims 50 and 52.

As per claim 53, Schnack in view of Hahn method as claimed in any preceding claim.

Schnack does not teach a method of quantifying the ventricular system by counting the

number of voxels of the ventricular system extracted by a method and multiplying this

count by voxel volume.

Hahn teaches a method of quantifying the ventricular system by counting the number of

voxels of the ventricular system extracted by a method and multiplying this count by

voxel volume **(Hahn: abstract: "quantification"; page 3, paras 42 and 51; page 4,**

para 58; page 5, paras 82-97).

Claims 2 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over

"Automatic Segmentation of the Ventricular System from MR Images of the Human

Brain", NeuroImage 2001, May 2001, Vol. 14, pages 95-104 (Schnack) and USPGPubN

20030068074 (Hahn) as applied to claim 1 above, and further in view of

"Anatomical−driven segmentation of the 3rd and 4th ventricles in MR data" Proceedings

of the First Joint BMES/EMBS Conference, Atlanta, GA, USA,

13−16 Oct. 1999 (Chung).

As per claim 2, Schnack in view of Hahn teaches a method according to claim 1,

wherein the steps of defining multiple ROIs, defining seed points and growing images

are applied first to one or more **(interpreted as meaning that only one of the**

following is required) images of a third ventricle (V3), and then to the left and right

ventricles (VLL and VLR) for controlling leakage and connections **(arguments made in**

rejecting claim 2 are analogous to arguments for rejecting claim 1).

Schnack discloses the limitations claimed above except for defining multiple ROIs,

defining seed points and growing images are applied first images of a third ventricle

prior to the same processes being applied to the left and right ventricles. It would have

been obvious for one of ordinary skill in the art at the time the invention was made to

have a different order of operation since it has been held that a mere reversal of the

essential working parts of a system involves only routine skill in the art. *In re Einstein,* 8

USPQ 167.

Schnack in view of Hahn does not teach then to one or more images of the fourth

ventricle (V4).

Chung teaches then to one or more images of the fourth ventricle (V4) **(Chung:**

abstract).

Thus, it would have been obvious for one of ordinary skill in the art at the time the

invention was made to implement the teachings of Chung into Schnack since Schnack

suggests a system for segmenting the left, right, and 3rd ventricles using region growing

techniques in general and Chung suggests the beneficial use of a system for

segmenting the 4th ventricle using region growing techniques in the analogous art of

image processing. It would have been obvious for one of ordinary skill in the art at the

time the invention was made to implement the also segment the additional 4th ventricle

since "The ventricular system is a connected structure and could, therefore, in principle,

be segmented with one region-growing operation", as stated by Schnack (page 2, col 2,

para 2). It is common an obvious to use multiple starting seed-points to segment a

single and connected region of interest since "owing to the partial volume effect, parts of

the system appear not connected on the image" (Schnack: page 2, col 2, para 2).

As per claim 35, Schnack in view of Hahn teaches a method according to any preceding

claim, wherein the step of growing the image of the fourth ventricle (V4) comprises the

steps **(Limitations present only within the preamble are not given patentable

weight)**: 1) subdividing into two subregions 1, and 2, by the axial plane passing

through the seed point, subregion 1 including the part superior to and subregion 2

including the part inferior to the axial plane; and 2) growing on axial slices, dorsally in

subregion 1 and ventrally in subregion 2 starting from the axial slice containing the seed

point **(Schnack: page 97 – page 99)**.

Schnack in view of Hahn does not teach subdividing V4 into two subregions; including

the part of V4 superior to the axial plane; and growing V4 on axial slices.

Chung teaches subdividing V4 into two subregions; including the part of V4 superior to

the axial plane; and growing V4 on axial slices **(Chung: abstract)**.

Allowable Subject Matter

Claims 48 and 49 are objected to as being dependent upon a rejected base claim, but

would be allowable if rewritten in independent form including all of the limitations of the

base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Atiba Fitzpatrick whose telephone number is (571) 270-

5255. The examiner can normally be reached on M-F 10:00am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Samir Ahmed can be reached on (571)272-7413. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call

800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Atiba Fitzpatrick

Patent Examiner

/Samir A. Ahmed/
Supervisory Patent Examiner, Art Unit 2624